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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,000	02/21/2007	Yuriko Taniguchi	291355US0PCT	7759

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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
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1652

NOTIFICATION DATE	DELIVERY MODE
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04/01/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/580,000	Applicant(s) TANIGUCHI ET AL.	
	Examiner HOPE A. ROBINSON	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/19/10.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4, 7-13 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4, 7-13 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/19/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. Applicant's response to the Office Action mailed September 24, 2009 on January 19, 2010, is acknowledged.

Claim Disposition

2. Claims 2-4, 7-13 and 16 are pending and are under examination.

Withdrawn-Specification Objection

3. Previous objections to the specification are withdrawn by virtue of submission of an amendment.

Claim Objection

4. Claims 2 and 10-11 are objected to because of the following informalities:

For clarity and precision of claim language it is suggested that claim 2 is amended to read for example,

“A method for reducing the effect of a fructosyl lysine compound in an assay of [[a glycosylated protein contained in]] a glycosylated protein-containing sample,

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the method comprising treating the sample with a protease to release
free fructosyl valine or fructosyl valylhistidine,

[[reacting an enzyme for assaying fructosyl valine or fructosyl valylhistidine]]

reacting a fructosyl amino acid oxidase with the glycated protein-containing sample

[[with the released fructosyl valine or fructosyl valylhistidine]] at a pH of 4.0 to

7.0 to produce [[a product]] hydrogen peroxide,

measuring the hydrogen peroxide [[product of the reacting at a pH of 4.0 to 7.0]]; and

correlating the measuring of the hydrogen peroxide [[product to]] with the presence or
level of glycated protein in the sample". See claims 10 and 11 which have similar language.

Correction is required.

Information Disclosure Statement

5. The Information Disclosure Statement filed on January 19, 2010 has been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

Maintained and Amended-Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 2-4, 7-13 and 16 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claims 2-4, 7-13 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the claims do not set forth how the “effect of a fructosyl lysine is reduced”. Claim 2 for example, recites “treating with a protease” and “reacting an enzyme”, however, the claim language remains unclear as to how “the effect of a fructosyl lysine is reduced”. The claim language does not adequately establish how the measuring of the product in the presence or level of glycated protein in the sample leads to a reduced effect of a fructosyl lysine compound. The claim remains confusing with respect to “measuring the product” and it is unclear what “product” is measured, and what is being measured, is a property of the fructosyl lysine compound measured or a property of the enzyme used in the assay, measured.

New-Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 2-4, 7-13 and 16 are rejected under 35 U.S.C. 102(a) as being anticipated by Hirokawa et al. (Biochemical and Biophysical Research Comm., Vol. 311, pages 104-111, July 2003, cited on the IDS filed 9/22/08).

Hirokawa et al. disclose a protease from *Aspergillus* that could efficiently liberate fructosyl peptides from HbA_{1c} (see page 104). The reference teaches a fructosyl peptide oxidase (FPOX) that is active against fructosyl peptides that can be used to measure HbA_{1c}. Hirokawa et al. disclose a pH of 6.5 and 8 (page 106), thus anticipates the recited pH range of 4 to 7. Hirokawa et al. teach that fructosyl amino acid oxidase (FAOX) or amadoridase catalyzes the oxidative deglycation of glycated amino acids to produce the corresponding amino acids, glucosone and hydrogen peroxide (see page 104).

Therefore, the limitations of the claims are met by the reference.

Response to Applicant's Arguments:

8. The amendment filed has been considered in full. Note that the objections of record are withdrawn, however, new objections are made over the claims for the reasons set forth above. The rejection under 35 USC 112 second paragraph remains and has been amended based on modifications to the claims. Applicant state that the claims have been amended thus the 112, second paragraph rejection should be withdrawn. This argument is not persuasive because the issue remains that the "effect"

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is not clear in the claim language. The instant method is directed to a method of reducing effect of a fructosyl lysine compound and the claim establishes that a protease is used in an assay, however, there is no indication as to what effect is reduced and how exactly that is measured. Thus, the rejection remains.

Previous rejection under 35 USC 102 (b) is withdrawn, thus applicant's comments are moot. However, note that a new ground of rejection has been instituted under 25 USC 102(a) for the reasons set forth above.

Conclusion

9. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652